

## REMARKS

### **Status of the claims:**

Claims 1, 6, 25-38, and 42-44 are hereby amended, and new claims 46-57 have been added. As such, claims 1, 6, and 25-57 are presently pending. Entry of this amendment is respectfully requested. A current claim listing is presented above with status identifiers for each claim, in accordance with 37 C.F.R. §1.121(c).

No new matter is introduced by this amendment. For example, claims 6, 25-27, 29-32, 34-38, and 42-44 are amended merely to maintain proper antecedent basis. Blood, saliva, and buccal cells (as recited in new claim 47) are set forth on page 45 (lines 18-20) of the specification (which recites blood, saliva, and buccal swabs). The term “correlating” (as recited in new claims 52-57) is used at least in original claim 1 (“correlated”). Computer software (as recited in new claims 53, 55, and 57) is described at least in the “Computer-Related Embodiments” section of the specification (pp. 112-116).

### **Rejections under 35 USC §112, first paragraph (new matter):**

The Examiner rejected claims 26, 31, and 36 under 35 USC §112, first paragraph, because reference to “the LPA gene” allegedly constitutes new matter. The Examiner also rejected claims 38-45 under 35 USC §112, first paragraph (new matter), because reference to “providing a report of the identity of the SNP” and “report is in paper form or computer readable medium form” allegedly constitutes new matter.

With respect to reference to “the LPA gene”, Applicants respectfully assert that this does not constitute new matter. For example, reference to the LPA gene is made at least in Table 2. In particular, gene number 67 in Table 2 (corresponding to genomic sequence SEQ ID NO:12227), which contains the context sequence of SEQ ID NO:19350 of the instantly claimed SNP, is identified in Table 2 as having the gene symbol “LPA”, and “APOLIPOPROTEIN(a);LPA” is indicated for OMIM information for this gene.

With respect to reference to “providing a report of the identity of the SNP” and “report is in paper form or computer readable medium form”, Applicants respectfully assert that this does not constitute new matter. For example, providing a report of a test result (e.g., the identity of a SNP), including paper reports or reports on computer readable medium, is well known in the art

and its disclosure is implicit in the specification. As an example of an implicit disclosure in the specification, page 62 (line 31) through page 63 (line 1) states that "...the subject can be motivated to begin simple life-style changes (e.g., diet, exercise)...", and it would be recognized that for a subject to be motivated to begin simple life-style changes, it would need to be reported to the subject that they possess the susceptibility allele(s). Further, one of skill in the art would recognize that such a report could be a paper report or provided on computer readable medium. Accordingly, references to "providing a report of the identity of the SNP" and "report is in paper form or computer readable medium form" are at least implicitly disclosed in the specification and would be well-known to one of skill in the art.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 USC §112, first paragraph, for allegedly including new matter.

**Rejection under 35 USC §112, first paragraph (enablement):**

Claims 1, 6, and 25-45 are rejected under 35 USC §112, first paragraph, for alleged lack of enablement. In maintaining this rejection, the Examiner states, in part, that if a person is a heterozygote with a GA genotype, it is unclear how the person may be at both an increased and a decreased risk for coronary stenosis, and that the specification allegedly fails to provide any enablement for heterozygotes being either at increased or decreased risk of coronary stenosis. The Examiner further states that the claims are broadly drawn to the detection of any polymorphic content that is "represented by position 101 of SEQ ID NO:19350", where the specification provides no limitations as to what is required for any polymorphic position in the human genome to be "represented by position 101 of SEQ ID NO:19350".

With respect to the aspect of this enablement rejection relating to the use of the language "as represented by" (in claims 1, 28, and 33), this phrase has been deleted (as discussed below in response to the indefiniteness rejection under 35 USC §112, second paragraph), thus obviating this aspect of the enablement rejection.

With respect to the aspect of this enablement rejection relating to heterozygosity, claims 1, 28, and 33 are hereby amended to specify homozygous genotypes in order to expedite prosecution, thus obviating this aspect of the enablement rejection.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 USC §112, first paragraph, for alleged lack of enablement.

**Rejection under 35 USC §112, second paragraph:**

The Examiner rejected claims 1, 6, and 25-45 under 35 USC §112, second paragraph, as being indefinite as the recitation of the phrase “as represented by” is unclear.

The “as represented by” language is hereby deleted for clarity. However, Applicants maintain that the context sequence of SEQ ID NO:19350 (and its complement) is not intended as a structural limitation beyond the SNP position itself (position 101 of SEQ ID NO:19350). A SNP itself is a single nucleotide position and therefore it is useful to refer to context sequence (e.g., SEQ ID NO:19350) surrounding a particular SNP in order to uniquely identify the SNP, since a single nucleotide position by itself is insufficient to uniquely identify a SNP. Thus, SEQ ID NO:19350 merely serves to provide a way of uniquely identifying and referring to the claimed SNP.

### Conclusions

In conclusion, in view of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance.

The Examiner is invited to contact the undersigned via telephone if a phone interview would expedite the prosecution of the instant patent application.

Respectfully submitted,

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Date: January 14, 2009

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